

**PATENT COOPERATION TREATY**  
**PCT**  
**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**  
(Chapter II of the Patent Cooperation Treaty)



(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 1060/853/PWO	<b>FOR FURTHER ACTION</b>		See Form PCT/PEA/416
International application No. PCT/GB2005/000503	International filing date (day/month/year) 19.02.2005		Priority date (day/month/year) 19.02.2004
International Patent Classification (IPC) or national classification and IPC INV. A61K7/48			
Applicant BOOTS HEALTHCARE INTERNATIONAL LIMITED			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 7 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> <i>(sent to the applicant and to the International Bureau)</i> a total of 4 sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> <i>(sent to the International Bureau only)</i> a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 16.12.2005	Date of completion of this report 19.05.2006		
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized officer Menidjel, R Telephone No. +31 70 340-3680		



**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/GB2005/000503

**Box No. I Basis of the report**

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
  - This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:
    - international search (under Rules 12.3 and 23.1(b))
    - publication of the international application (under Rule 12.4)
    - international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

**Description, Pages**

1-25 as originally filed

**Claims, Numbers**

1-32 filed with telefax on 16.12.2005

- a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3.  The amendments have resulted in the cancellation of:
  - the description, pages
  - the claims, Nos. 11
  - the drawings, sheets/figs
  - the sequence listing (*specify*):
  - any table(s) related to sequence listing (*specify*):
4.  This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
  - the description, pages
  - the claims, Nos.
  - the drawings, sheets/figs
  - the sequence listing (*specify*):
  - any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/GB2005/000503

**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:
  - the entire international application,
  - claims Nos. 28-32
    - because:
  - the said international application, or the said claims Nos. 28-32 relate to the following subject matter which does not require an international preliminary examination (specify):  
**see separate sheet**
  - the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
  - the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
  - no international search report has been established for the said claims Nos.
  - the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
    - the written form  has not been furnished  
 does not comply with the standard
    - the computer readable form  has not been furnished  
 does not comply with the standard
  - the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
  - See separate sheet for further details

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/GB2005/000503

**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes: Claims	1-32
	No: Claims	
Inventive step (IS)	Yes: Claims	1-32
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-27
	No: Claims	

**2. Citations and explanations (Rule 70.7):**

**see separate sheet**

**INTERNATIONAL PRELIMINARY  
REPORT ON PATENTABILITY  
(SEPARATE SHEET)**

International application No.  
PCT/GB2005/000503

**Re Item III**

**Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

- The subject-matter of claims 28-32 is related to a method for treatment of the human or animal body from surgery or therapy. Using its discretion, the present authority decided not to carry out an internal preliminary examination on that subject-matter (Article 34(4)(a) PCT in conjunction with Rule 67.1(iv) PCT).

For the assessment of the present claims 28-32 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1 - The following documents (D1,D2,D3) are referred to in this communication (Article 33(6) PCT); the numbering will be adhered to in the rest of the procedure:

D1: WO 03/063816 A (THE PROCTER & GAMBLE COMPANY) 7 August 2003 (2003-08-07)

D2: CH 647145 (DR. MED. PAUL HERZOG; KARIN HERZOG-THOMANDER) 15 January 1985 (1985-01-15)

D3: EP-A-0 696 451 (REVLON CONSUMER PRODUCTS CORPORATION) 14 February 1996 (1996-02-14)

**2. Novelty (Article 33(2) PCT)**

- The subject-matter of present claims 1-32 is considered as novel over the cited prior art for the following reasons (Article 33(2) PCT):

- Document D1 (WO03063816) describes a topical care composition comprising a hydrolysed milk protein, salicylic acid and a cosmetic carrier (Cf. D1, page 2, last paragraph-page 3, paragraph 2; page 6, last paragraph-page 7, paragraph 1; page 10, paragraph 2; page 13,

**INTERNATIONAL PRELIMINARY  
REPORT ON PATENTABILITY  
(SEPARATE SHEET)**

International application No.

**PCT/GB2005/000503**

paragraph 1-page 16, paragraph 2; claims 1-11).

- Document D2 (CH647145) describes a cosmetic product comprising milk protein, hydrogen peroxide and salicylic acid (Cf. D2, the whole document).
- Document D3 (EP0696451) describes a cosmetic formulation comprising salicylic acid and a hydrolysed vegetable protein (Cf. D3, page 2, line 49-line 52; page 3, line 14-line 36; example 1; claims 1-9).
- None of the cited documents D1-D3 refers to a skin care composition with a pH in the range 2.5-6.0, the composition comprising 0.1-5% by weight salicylic acid or a salt thereof and wherein the ratio of salicylic acid or salt thereof to hydrolysed milk protein is in the range from 2:1 to 15:1 parts by weight.

**3. Inventive Step (Article 33(1),(3) PCT)**

- The subject-matter of present claims 1-32 is considered as being inventive for the following reasons (Article 33(1),(3) PCT):
  - The problem to be solved by the present application is to provide a skin care composition effective in the treatment of acne vulgaris which comprises salicylic acid with one or more oil control agents.
  - The solution proposed in the present application is a skin care composition suitable for topical application to the skin, the composition comprising salicylic acid or a salt thereof and hydrolysed milk protein as described in present independent claim 1 and an article impregnated with said skin care composition (see independent claim 25).
  - Document D1, which is considered as the closest prior art, describes a topical care composition comprising a hydrolysed milk protein, salicylic acid and a cosmetic carrier.
  - The difference between the teaching of the closest prior art and the subject-matter of present claims 1-32 is a skin care composition and said article impregnated with said skin care composition wherein the specific concentrations of salicylic acid or a salt thereof and hydrolysed milk protein within the composition.

**INTERNATIONAL PRELIMINARY  
REPORT ON PATENTABILITY  
(SEPARATE SHEET)**

International application No.

PCT/GB2005/000503

- Starting from D1, the skilled person had no incentive to come to the claimed solution and therefore, the subject-matter of present claims 1-32 is considered as being inventive according to Article 33(1),(3) PCT.
- Claims 28-32 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

**4. Industrial Application (Article 33(4) PCT)**

- The subject-matter of present claims 1-27 is considered to be industrially applicable; claims 1-27 therefore, satisfy the criterion set forth in Article 33(4) PCT.

1060/853/P/WO Amended claims 12.05

26

Claims

1. A skincare composition with a pH in the range 2.5-6.0, suitable for topical application to the skin, the composition comprising 0.1-5% by weight salicylic acid or a salt thereof and hydrolysed milk protein, wherein the ratio of salicylic acid or salt thereof to hydrolysed milk protein is in the range from 2:1 to 15:1 parts by weight.
- 10 2. A composition as claimed in Claim 1, which comprises salicylic acid.
3. A composition as claimed in Claim 2, wherein the concentration of salicylic acid is at least 1% by weight.
- 15 4. A composition as claimed in Claim 2, wherein the concentration of salicylic acid is less than 3% by weight.
5. A composition as claimed in Claim 2, wherein the concentration of salicylic acid is in the range from 1% to 3% by weight.
- 20 6. A composition as claimed in Claim 1, wherein the concentration of hydrolysed milk protein is at least 0.05% by weight, and most preferably at least 0.1% by weight.
- 25 7. A composition as claimed in Claim 1, wherein the concentration of hydrolysed milk protein is less than 1% by weight.
8. A composition as claimed in Claim 1, wherein the concentration of hydrolysed milk protein is in the range from 0.1% to 1.0% by weight.

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9. A composition as claimed in claim 1, wherein the concentration of salicylic acid is in the range from 0.5 to 4% by weight, more preferably from 0.5 to 2% by weight and the concentration of hydrolysed milk protein is in the range from 0.08 to 2%, more preferably from 0.1 to 0.5 % by weight.

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10. A composition as claimed in any preceding claim, wherein the ratio of salicylic acid or salt thereof to hydrolysed milk protein is in the range from 5:1 to 12:1 parts by weight.

10 11. A composition as claimed in any preceding claim, wherein the pH is in the range from 2.5 to 4.0.

12. A composition as claimed in any preceding claim further comprising one or more further topically active skincare agents selected from an anti-15 microbial or anti-bacterial compound, an anti-viral compound, an anti-fungal compound, an anti-inflammatory compound and an anthelmintic compound.

13. A composition as claimed in claim 12 wherein the anti-bacterial agent is a peroxide anti-bacterial agent.

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14. A composition as claimed in any preceding claim, which has the form of an aqueous or oily solution or dispersion or emulsion or a gel.

15. A composition as claimed in Claim 14, which is in the form of an emulsion.

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16. A composition as claimed in Claim 15, wherein the emulsion is an oil-in-water emulsion.

30 17. A composition as claimed in Claim 15, wherein the emulsion is a water-in-oil emulsion.

1060/853/P/WO Amended claims 12.05

28

18. A composition as claimed in claim 14, which is in the form of an aqueous gel.
19. A composition as claimed in any preceding claim, which further 5 comprises a gelling and/or a thickening agent.
20. A composition as claimed in Claim 19, wherein the gelling agent is a copolymer of acryloyl dimethyl tauric acid or a salt thereof.
- 10 21. A composition as claimed in any preceding claim, which comprises an aqueous solvent system.
22. A composition as claimed in Claim 21, wherein the solvent system is a mixed solvent system comprising water in admixture with a co-solvent. 15
23. A composition as claimed in Claim 22, wherein the co-solvent is an alcohol.
24. A composition as claimed in any preceding claim, which comprises one 20 or more excipients selected from the group consisting of emulsifiers, emollients, lipids, humectants or moisturisers, binders, conditioning agents, emulsion stabilising salts, preservatives, chelating agents or sequestering agents, abrasives, pH adjusters, surfactants, perfumes and colourings.
25. An article comprising a fibrous substrate impregnated with a skincare 30 composition with a pH in the range 2.5-6.0, suitable for topical application to the skin, the composition comprising 0.1-5% by weight salicylic acid or a salt thereof and hydrolysed milk protein, wherein the ratio of salicylic acid or salt thereof to hydrolysed milk protein is in the range from 2:1 to 15:1 parts by weight.

1060/853/PWO Amended claims 12.05

29

26. An article as claimed in claim 25, wherein the fibrous material is impregnated with the skincare composition in an amount in the range from 10 to 30% by weight, preferably from 15 to 25% by weight and most preferably from 18 to 22% by weight of the fibrous material.

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27. An article as claimed in either one of claims 25 or 26 comprising cellulose or cotton fibres or a mixture thereof.

28. A method for the prophylactic or remedial treatment of acne, which method comprises the topical application to the skin of a patient of a skincare composition with a pH in the range 2.5-6.0, suitable for topical application to the skin, the composition comprising 0.1-5% by weight salicylic acid or a salt thereof and hydrolysed milk protein, wherein the ratio of salicylic acid or salt thereof to hydrolysed milk protein is in the range from 2:1 to 15:1 parts by weight.

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29. A method as claimed in Claim 28, which is a cosmetic method.

30. A method as claimed in Claim 28, which is a therapeutic method.

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31. The use of hydrolysed milk protein in a composition comprising 0.1-5% by weight salicylic acid or a salt thereof and having a pH in the range 2.5-6.0, wherein the ratio of salicylic acid or salt thereof to hydrolysed milk protein is in the range from 2:1 to 15:1 parts by weight, for the prophylactic or remedial treatment of acne by topical application of the composition to the skin.

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32. The use as claimed in claim 31 wherein salicylic acid or a salt thereof and hydrolysed milk protein are the sole active ingredients in the composition.

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